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EXAMINER

KREMER, MATTHEW J

ART UNIT PAPER NUMBER

3736

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/798,596

Applicant(s)

MANNHEIMER ET AL. 

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/10/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,942,877 to Sakai et al. (Sakai). Sakai teaches a light emitter 20, a detector 25, and a memory 56. (Fig. 1 of Sakai). Claims 1-12 recite limitations that attempt to claim particular data that is stored in the memory. A memory only stores data in the forms of 1's and 0's and such data are not structurally distinct from any other data that are stored as 1's and 0's. It is the connection to microprocessors that provide meaning to the data in the memory. Without this connection to provide meaning to the data, there is not structural distinction from one data set to another.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 6-9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,623,248 to Sperinde (cited by Applicant) in view of U.S. Patent 4,942,877 to Sakai et al. (Sakai)(cited by Applicant). Sperinde discloses an oximeter in which the oxygen saturation level is computed by using a formula which uses the ratio of one pair of intensity signals when the oxygen saturation level is relatively low and with another formula which uses the ratio of another pair of intensity signals when the oxygen saturation level is relatively high. (Abstract of Sperinde). Each formula has a different set of coefficients. Sperinde does not disclose a sensor memory, which stores the coefficients for use in the formulas. However, the method of Sperinde requires the calibrated coefficients to be stored in a memory to carry its steps since the coefficients need to be recalled for various different measurements over time. Sakai discloses a memory used to store coefficients for the determination of oxygen saturation. The memory is located in the sensor unit. (column 12, lines 6-37 of Sakai). Such a memory would fulfill the requirement of the necessary storage of the coefficients in the method of Sperinde. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the memory of Sakai in the device of Sperinde since the method and device of Sperinde requires a device for data storage of the coefficients and Sakai et teaches one such method. In regard to claim 1, Sperinde teaches a light emitter and light detector. (Fig. 4 of Sperinde). In regard to claims 2 and 7, the coefficients are based on experiments using specific wavelengths. In regard to claims 3, 6, and 8, Sperinde discloses a threshold point in the form of saturation values for determining which of the two formulas to use. (column 5,

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line 46 to column 6, line 7 of Sperinde). In regard to claims 4 and 9, the combination also teaches the use of a non-linear formula. (Fig. 5A of Sperinde).

5. Claims 1-3, 5-8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,086,915 to Kofsky et al. (cited by Applicant) in view of U.S. Patent 4,942,877 to Sakai et al. (cited by Applicant). Kofsky et al. teaches an oximeter with multiple sets of coefficients for use in calculating oxygen saturation depending on the range of total hemoglobin concentration. (column 8, lines 8-24 of Kofsky et al.). The different hemoglobin concentrations would cause different saturation readings for a particular set of coefficients. Kofsky et al. does not teach that the coefficients are stored in the sensor. It is well known in the art to use memories in sensors to store coefficients. (column 12, lines 6-37 of Sakai et al.). Placing sensor-specific threshold values in the memory of a particular sensor would allow more accurate calculations while removing the need to store the calibration values in the oximeter for a plurality of different sensors, i.e., different sensors can then be used with the oximeter. Further, Sakai et al. suggests that the coefficients used in calculating oxygen saturation can be stored in either the sensor or in the main unit. (column 12, lines 6-37 of Sakai et al.). This suggestion implies that placing the calibrated coefficients in the sensor memory is functionally equivalent to placing the calibrated coefficients in the memory of the main unit. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor of Kofsky et al. to include a memory in the sensor as disclosed by Sakai et al.

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since sensor-specific calibration values in the memory of a particular sensor would allow more accurate calculations while removing the need to store the threshold value in the oximeter for a plurality of sensors and Sakai implies that using a memory in the sensor is functionally equivalent to using a memory in the main unit. In regard to claim 1, the combination teaches a light source 1, a light detector 9 (Fig. 1 of Kofsky), a memory (column 12, lines 6-37 of Sakai et al.), and storing multiple sets of coefficients for use in calculating oxygen saturation depending on the range of total hemoglobin concentration. (column 8, lines 8-24 of Kofsky et al.). The selection of the coefficients depends upon the values obtained from the light detector 9. In regard to claims 5-6 and 10, the combination teaches a plurality of coefficients P_i and provides an example of four sets. (column 8, lines 8-24 of Kofsky et al.). In regard to claim 12, Kofsky et al. teaches that many sets of coefficients can be used as necessary (column 8, line 22-24 of Kofsky et al.), which implies that interpolation is used.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 4-5, and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-5 and 8 of U.S. Patent No. 6,801,797 to Mannheimer et al. (Mannheimer). Although the conflicting claims are not identical, they are not patentably distinct from each other. In regard to claim 1 of the present application, claim 4 of Mannheimer claims an "oximeter sensor comprising: a light emitter for directing light at a patient; a light detector mounted to receive light from said patient; and a memory storing coefficients for use in at least one formula for determining oxygen saturation...wherein...first and second sets of coefficients are used in different formulas." Claim 4 of Mannheimer is claiming a memory storing coefficients for use in first and second different formulas for determining oxygen saturation since first and second sets of coefficients are used in different formulas. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 of Mannheimer claims a memory, which is narrower in scope, than the memory of claim 1 of the present application. Claim 4 of Mannheimer meets all the limitations set out in claim 1 of the present application and it would be obvious that the sensor of claim 1 of the present application is actually the sensor of claim 4 of Mannheimer.

In regard to claim 4 of the present application, claim 4 of Mannheimer claims "wherein said different formulas are nonlinear formulas", which is narrower in scope than claim 4 of the present application, which claims "wherein at least one of said

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different formula is a nonlinear formula". Claim 4 of Mannheimer meets all the limitations set out in claim 4 of the present application and it would be obvious that the sensor of claim 4 of the present application is actually the sensor of claim 4 of Mannheimer.

In regard to claim 1 of the present application, claim 5 of Mannheimer claims an "oximeter sensor comprising: a light emitter for directing light at a patient; a light detector mounted to receive light from said patient; and a memory storing coefficients for use in at least one formula for determining oxygen saturation...wherein said first and second sets of coefficients are used in different formulas". Claim 5 of Mannheimer is claiming a memory storing coefficients for use in first and second different formulas for determining oxygen saturation since first and second sets of coefficients are used in different formulas. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 5 of Mannheimer claims a memory, which is narrower in scope, than the memory of claim 1 of the present application. Claim 5 of Mannheimer meets all the limitations set out in claim 1 of the present application and it would be obvious that the sensor of claim 1 of the present application is actually the sensor of claim 5 of Mannheimer.

In regard to claim 5 of the present application, claim 5 of Mannheimer claims "wherein said different formulas are linear formulas".

In regard to claim 11 of the present application, claim 8 of Mannheimer claims an oximeter system comprising "an oximeter sensor comprising a light emitter for directing light at a patient; a light detector mounted to receive light from said patient; and a

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memory storing a plurality of alternate values of oxygen saturation or signal ratiometric values used to determine oxygen saturation, said plurality of values being dependent on a mean wavelength of said light emitter", which is narrower in scope than claim 11 of the present application. Claim 8 of Mannheimer meets all the limitations set out in claim 11 of the present application and it would be obvious that the sensor of claim 11 of the present application is actually the sensor of claim 8 of Mannheimer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 571-272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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